

Application No.: 10/633,107

Docket No.: P-5315C1

REMARKS

Claims 1-23 are pending in this application. Claims 1, 5-12, 16, 21 and 23 have been amended and claims 4, 13-15 have been cancelled herein. Reconsideration and withdrawal of the rejections to the claims are respectfully requested in light of the previous amendments and following remarks.

Applicants acknowledge the indication that a restriction requirement may be applied in the future to the present application and reserve the right to overcome such requirement in the future.

The Examiner has maintained her rejection of claims 1-23 under 35 U.S.C. §102(e) as being clearly anticipated by Schoenfeld et al., U.S. 6,283,941 (hereinafter "Schoenfeld"). Independent claims 1, 7 and 12 have been amended herein. Specifically, claim 1 has been amended to recite that the spring element extends proximally from the base and urges the barbs of the locking element in the direction of the inside surface of the syringe barrel. Moreover, claim 1 has been amended to recite that the base portion of the locking element is generally trough-shaped and includes a first and second side wall and a bottom wall. Claims 7 and 12 have also been amended to more clearly recite the structure of the locking element and the function of the spring member of the locking element similar to claim 1.

The Examiner had stated that Schoenfeld includes a spring type fit on tab 110 of Fig. 10. The Examiner states that tab 110 of Schoenfeld anticipates the third leg 68 (or spring element as recited in claims 1 and 7) of the present invention. In response to applicants' previous arguments, the Examiner has stated she has interpreted claim 1, to be that the spring element helps the locking device move in one direction and not the other, so that the plunger moves distally and not proximally. Moreover, the Examiner states that it appears from Fig. 10 of the present application that the third leg helps ease movement in the distal direction just as the Schoenfeld tab 110 does. The Examiner further states that the only mention of the third leg 68 in the present application is in paragraph [0028]. Applicants believe that the Examiner is referring to paragraph [0030] which states that the function of the spring member is to urge the barbs towards the inside surface of the barrel. There is additional discussion of the spring member in paragraphs [0026] and [0027].

With respect to Examiner's interpretation of claim 1, the claim has been amended to clarify that the spring member extends proximally from the bottom wall of the base and urges the barbs towards the inside surface of the barrel. The Examiner's interpretation regarding

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the spring element is only partially correct. The spring element urges the barbs towards the inside surface of the barrel, as now reflected in claim 1, which in turn prevents the locking element from moving distally and while allowing the locking element to move proximally. By properly positioning the locking element on the plunger rod during manufacture, the plunger rod may move only one time in the proximal direction and one time in the distal direction.

Furthermore, it is respectfully submitted that the Examiner's interpretation that the spring element 68 of the present invention helps to ease movement in the distal direction, as the tab 110 of Schoenfeld does, is incorrect and not supported by either the specification or the figures of the present application. Schoenfeld recites that the semicircular tab 110 extends distally from back 60 and that it counterbalances tab 80 and prevents jamming of the clip during plunger movement. The tab 110 of Schoenfeld does this by being "bent radially inwardly towards the plunger." Thus, tab 110 provides for smooth distal movement of the plunger and clip without scraping the inside of the barrel. Finally, when the plunger of Schoenfeld is fully moved in the distal direction, tab 110 is actually forced between the plunger seal 52 and the sidewall 17. (See, generally, Col. 18, ln. 65 – Col. 19, ln. 6).

The spring element/third leg as recited in independent claims 1, 7 and 12 of the present invention does not act in the same manner nor does it perform the same function. As stated in the specification of the present application, the spring member urges the barbs towards the inside surface of the barrel (See Paragraph [0030]). As illustrated in the figures of the present application, the spring member 68 includes bends 68A and 68B. The first bend 68A, bends the spring member towards the inside surface of the barrel, away from the plunger rod, in the opposite direction disclosed in Schoenfeld. The second bend 68B bends the proximal portion of the spring element back towards the plunger rod. However, as shown in Fig. 10 and discussed at paragraph [0027] the spring element extends beneath the plane of the bottom wall 58 of the base. Figs. 4-6 clearly show that the spring element is in contact with the inside surface of the barrel at bend 68B. This contact allows the spring member to resiliently urge the barbs towards the inside surface of the barrel. Schoenfeld, however, states that the tab 110 bends inwardly towards the plunger rod and provides smooth distal movement of the plunger rod without scraping the barrels surface. Moreover, to accomplish its stated function of counterbalancing tab 80, the tab 110 must be in contact with the plunger rod. As shown in Figs. 5 and 6 of the present application, upon completion of distal

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movement of the plunger rod, spring member 68 is not even in contact with the plunger rod, but only the inside surface of the barrel. Since it is a spring member pressing upon the inside surface of the barrel, the barbs are thus urged towards the inside surface of the barrel.

Yet another distinction between the tab 110 of Schoenfeld and the spring element as recited in amended claim 1, is that the spring element extends in the proximal direction, while the tab 110 of Schoenfeld extends in the distal direction. Thus, the tab 110 is not urging the locking points of the Schoenfeld device towards the inside surface of the barrel. Rather the tab 110, is bent towards the plunger rod and holding onto the plunger rod to ease the movement of the locking spring. In this manner, the tab 110 cannot urge the locking points towards the inside surface of the barrel. Additionally, tab 80 of Schoenfeld cannot be considered to anticipate to the spring element since it is coplanar with back section 60 and touches the plunger teeth to prevent rocking motion of the clip to ensure alignment between the clip and the plunger. In no way does Schoenfeld disclosed that either tab 110 or 80 are spring elements that urge the locking points towards the inside surface of the barrel.

Rather Schoenfeld discloses a locking spring 40 that is generally circular in shape with one side open. As the Examiner suggests, the entire locking spring is in fact springy or resilient. Applicants respectfully submit, however, that the manner in which the locking spring of Schoenfeld is resilient is different than the spring member of the present invention. Schoenfeld states that the resiliency "allows the spring clip 40 to flex radially inwardly and outwardly..." (Col. 16, In. 57-59). More specifically the resiliency of teeth 83 and 85 allows, via radial flexing of the clip, the teeth to cam over and ride on the inclined surfaces 31 or convex surfaces of the ratchet teeth of the plunger. (Col 18, Ins. 14-17). Thus the shape and resiliency of the device allows for the discussed radial flexing movement. (Col. 18, Ins. 53-55). It is the outward radial resiliency of the spring locking clip that embeds the contact points into sidewall 17. (Col. 18, Ins. 47-48).

On the other hand, the present invention, as recited in claims 1, 7 and 12, does not teach radial flexing, or a circular shaped locking spring with an opening to allow such radial flexing to occur. Rather, the locking element includes a trough shaped base portion. Extending from the base portion are two opposing legs and a spring element. The spring element is pivotally attached to the bottom wall of the base in the axial direction. This spring element urges the barbs towards the inside surface of the barrel through this resilience in the axial direction. In fact, there is no radial resiliency in among the spring element and the

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barbs, since there is no continuity between the spring elements and the opposing legs. In fact, each of the opposing legs and the spring element extend from the base individually with spaces therebetween.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. §2129 (quoting *Verdegall Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Schoenfeld fails to disclose a spring member/third leg as recited in each of the independent claims. Moreover, Schoenfeld does not disclose opposing legs and a spring member that extend proximally from the base of the locking element. Since Schoenfeld fails to disclose each of the elements of independent claims 1, 7 and 12, it is respectfully submitted that the 35 U.S.C. §102(e) rejection should be withdrawn with respect to each of these claims.

Moreover, each of the remaining claims depend from, either directly or indirectly, one of independent claims 1, 7 or 12. Thus, for at least the reason set forth above, it is respectfully requested that the 35 U.S.C. §102(e) rejection be withdrawn with respect to each of the remaining pending claims.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that she telephone applicants' attorney at (201) 847-6797 in order to overcome any additional objections which she might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 02-1666 therefor.

Dated: November 21, 2005

Respectfully submitted,

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